

9 by reference to the dial and to the above-mentioned leaflet, were claimed to enable the consignee to determine the patient's condition.

LIBELED: 4-11-56, Dist. N. Mex.

CHARGE: 502 (a)—the labeling of the device, when shipped and while held for sale, contained false and misleading representations that the device was effective for diagnosing impaired digestion, abnormal conditions of the blood and tissues, the state of the body's cell life, the condition of the body's temperature regulating mechanism, the condition of the hair, teeth, eyes, and nails, the status of the iron balance in tissue digestion, the condition of one's bones, muscular functions, thyroid gland, brain, nerves, blood cell development, a condition of retarded growth, skin conditions, the condition of one's circulation and muscle function, abnormal tissue respiration, whether or not one requires a blood builder, a condition of general poisoning, inflammation, tissue degeneration, conditions due to bacterial toxins, a poisoned condition of the bowels, hyperacidic condition of the blood, conditions associated with excessive uric acid in the system, catarrh, streptococcus infection, staphylococcus infection, cancer, tuberculosis, conditions caused by excessive pressure on the nerves, sarcoma, ulcers, the state of one's glandular activity, calculi, anemia, fibroids, goiter, infestation by intestinal parasites, cysts, tumors, conditions due to scar tissue formation, rheumatism, cholelithiasis, eczema, and a toxic condition caused by excessive amounts of aluminum in the body.

2 502 (f) (1)—the labeling of the device, when shipped and held for sale, failed to bear adequate directions for use for diagnosing the conditions appearing in its labeling, since the labeling bore no directions for diagnosing such conditions, and it is impossible to devise adequate directions for such purposes and conditions. The labeling of the device failed also to bear adequate directions for use for obtaining information concerning one's heart action, nerve energy, the nature of one's ailments, the causes of one's ailments, and one's mineral and vitamin deficiencies, which were the conditions for which the device was intended and for which it was offered in the newspaper advertisements while held for sale.

DISPOSITION: 5-11-56. Default—delivered to Food and Drug Administration.

DRUGS FOR VETERINARY USE

5006. S-M capsules. (F. D. C. No. 38425. S. No. 15-560 M.)

QUANTITY: 1,156 boxes at Stockton, Calif., in possession of the Stockton Veterinary Supply Co.

SHIPPED: At various times from New York, N. Y.

LABEL IN PART: (Box) "Dr. Saunders * * * S-M Capsules Sodium Sulfamethazine Highly Recommended for Treating Many Bacterial Infections Contents: 6 Capsules * * * Directions: For Cattle and Horses: One Capsule for each 500 pounds of body weight. If necessary repeat every 24 hours until better."

RESULTS OF INVESTIGATION: The article had been shipped in powder form in bulk drums labeled, in part, "Sulfamethazine"; and, after its receipt by the consignee, the article was encapsulated and repacked into boxes labeled as described above.

Analysis showed that the article was sulfamethazine and not sodium sulfamethazine as declared on the box label.

LIBELED: 9-15-55, N. Dist. Calif.

CHARGE: 501 (d) (2)—while held for sale, sulfamethazine had been substituted for sodium sulfamethazine, which the article was represented to be; 502 (a)—the label on the boxes of the article contained false and misleading representations that the article consisted of sulfamethazine and that it was an adequate and effective treatment for retained afterbirth, congested lungs, and acute mastitis in cattle, and distemper and colds in horses.

502 (f) (2)—the labeling of the article failed to warn that the article may cause severe toxic reactions and irreparable damage if the blood levels become too high; that constant supervision of the animals was essential during treatment; and that use of the article should be discontinued if toxic symptoms appeared.

DISPOSITION: 12-1-55. Consent—claimed by Stockton Veterinary Supply Co. and relabeled.

5007. Solu-Stilbestrol. (F. D. C. No. 38980. S. No. 26-201 M.)

QUANTITY: 23 1-gal. cans at Coon Rapids, Iowa.

SHIPPED: 12-28-54 and 4-1-55, from Chicago, Ill., by Vitamins, Inc.

LABEL IN PART: (Can) "Vit Inc 1 Gal. Solu-Stilbestrol-50 Containing 50 gm. diethylstilbestrol with a solubilizing agent dissolved in 1 gal. molasses.

CAUTION: For manufacturing, processing or repackaging of the preparation of a new drug limited by federal law to investigational use. Control #15530 Manufactured by Vitamins, Inc. 809 W. 58th St. Chicago 21, Ill., U. S. A. For Manufacturing Use."

RESULTS OF INVESTIGATION: Diethylstilbestrol intended for feeding to cattle for increasing their weight is regarded as a "new drug" ingredient.

Vitamins, Inc., filed a new-drug application for the article on 6-10-55 and submitted data concerning the use made of the article by the consignee, Garst Co., Coon Rapids, Iowa. These data were verified by information obtained by Food and Drug inspectors and showed that Garst Co. mixed the diethylstilbestrol preparation with cattle feed and fed the resultant mixture to its animals for fattening purposes, and showed further that no scientific tests of any real nature were conducted in connection with the feeding. In such circumstances, the new-drug application was not made effective.

LIBELED: On or about 3-8-56, N. Dist. Iowa.

CHARGE: 502 (f) (1)—the label of the article, when shipped and while held for sale, did not bear adequate directions for use, and the article was not entitled to any exemption from that requirement since the article had not been used and was not being used only in the manufacture of a new drug limited to investigational use as provided in the regulations.

DISPOSITION: 4-24-56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5008. Various drugs. (F. D. C. No. 37994. S. Nos. 19-261/71 M.)

QUANTITY: 161 btl. of *Asmax* tablets, 151 btl. of *Lipolin*, 108 btl. of *Aratex* tablets, 6 btl. of *amino acid wafers*, 35 btl. of *Rectone* tablets, 50 btl. of *herbal diuretic tablets*, 56 14-oz. btl. and 13 8-oz. btl. of *Detoxo*, and 54 btl. of *Glutamins* tablets at Akron, Ohio.

*See also No. 5006.